BREAST CANCER MALPRACTICE CLAIMS

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Breast cancer, a disease now estimated to afflict 12 percent of women in this country, is a major public health issue for the United States.[1] Approximately 200,000 cases of breast cancer are newly diagnosed every year, and the disease annually causes the deaths of nearly 50,000 patients.[2]

Beyond the stark reality of epidemiologic data, this illness exacts a significant emotional toll. The threat of its potential appearance, the burden of its presence when diagnosed, and the consequences of its treatment pose a special if not unique invasion of bodily integrity and self-image for those afflicted.

Standard medical practice in the evaluation and treatment of breast cancer patients encompasses a broad and challenging level of professional skill, knowledge, care, and diligence.

A FEDERAL CASE

The patient, a 37-year-old dependent wife of an active duty military member, underwent a normal breast exam by her gynecologist in April 1985. She reported to the same provider a two-month history of fullness and tenderness in her right breast in March 1986, and he referred her to the general surgery clinic with a provisional diagnosis of fibrocystic disease, right greater than left.

The surgical consultation was chiefly recorded by a rotating medical student who evaluated the patient in April 1986 with an attending staff member. A negative family history for breast cancer was noted, and the patient had never undergone mammography. The breasts were described as small and symmetrical. There was a diffuse thickening of breast tissue on the right side throughout the medial inferior quadrant. The clinical impression was fibrocystic disease, and reevaluation at four weeks was ordered.

A general surgery house officer, with the same staff member attending as in April, provided re-evaluation in May 1986. Firm, diffuse breast tissue, with small cysts, was again detected throughout the inferior medial quadrant of the right breast. The clinical impression remained fibrocystic disease. The patient was advised to conduct self-examinations monthly and to return to clinic at six months. The medical record included a specific notation that mammography was not indicated.

Another attending general surgeon evaluated the patient in March 1987. He detected the same area of diffuse right breast tissue thickness at the inferior medial quadrant. He considered these findings to likely represent fibrocystic disease, but advised the patient a biopsy was necessary and ordered mammography.

The mammogram revealed multiple suspicious microcalcifications, without evidence of a distinct mass. A subsequent breast biopsy revealed intraductal and infiltrative cancer. At the time of mastectomy in March 1987, one of 17 axillary nodes was positive for disease.

A federal malpractice claim was filed in March 1988. Metastatic disease was diagnosed in August 1990, and multiple organ system involvement was detected in April 1991. The patient's husband retired in June 1991 to assume the primary responsibility for the care of three dependent children.

The malpractice claim was investigated initially at the local command, where it was concluded that the care rendered at the time of the 1986 evaluations was incomplete. The full investigation of this case revealed that the patient had been substantially reassured at the time of her 1986 assessments and, when seeking reevaluation later, she was unable to obtain a necessary appointment for some time. Ultimately, opinions were

secured with specialists from general surgery, oncology, pathology and radiology. They uniformly agreed that the diagnosis of breast cancer in this case was negligently delayed and that further studies should have been pursued in 1986 when the disease could have been diagnosed and treated.

This case was settled administratively, with a negotiated award and without litigation.

THE BREADTH OF PRECEDENT

In 1794, a Connecticut court issued the first written appellate opinion in the United States regarding medical malpractice. The case involved surgical care and the near immediate death of a woman who suffered a "scorfulous" breast lesion.[3]

In 1995, medical malpractice cases involving the diagnosis and treatment of breast cancer have become the most common form of liability claim filed against physicians in the United States. Specialists defending themselves in those cases include, among others, representatives from family practice, obstetrics-gynecology, internal medicine, general surgery, oncology, radiology, radiation oncology, and pathology.

The amount of money paid by medical liability insurance companies as indemnification for such cases makes them, by disease category, the most frequent cause for paid malpractice claims and a leader in the total amount of indemnification.

This publication and others similar, along with the traditional medical literature, have previously addressed this form of malpractice claim.[4] The frequency of those claims, their severity, and the experience of patients when serious errors arise in the diagnosis or treatment of breast cancer would appear to justify that level of attention.

THE PROFESSIONAL LITERATURE

Haagensen, in 1971, noted in his clinical series of 1,433 patients who had discovered their own breast cancers that 19 percent (270 cases) were initially misdiagnosed by physicians and that the average delay in diagnosis for those cases was 14 months.[5]

Foley and others internally reviewed the Armed Forces Institute of Pathology (AFIP) experience with breast cancer related malpractice claims in 1990.[6] Their study was drawn from 4,321 federal malpractice claims subjected to consultation by the Department of Legal Medicine at AFIP from 1980 through 1989. There were 80 claims related to the delayed diagnosis of breast cancer, and all were derived either from military medical services (77 cases) or other federal health agencies. The reviewers considered 56 (70 percent) of the study cases meritorious and substantiable malpractice claims. An error taxonomy was developed, and the most frequently encountered problems included failure to perform a biopsy (38 cases), especially when mammography was considered negative (19 cases), misreading of positive findings on mammography (5 cases), misreading of histopathology specimens (3 cases), inadequate biopsies (3 cases), and communication failures (3 cases). There were 68 closed cases, 51 (75 percent) with payment. Indemnification range from $6,000 to $1,000,000, with a median payment of $100,000 and a mean of $162,050.

Kern, in 1991, published a survey of all negligence trials involving the diagnosis of breast cancer retrieved through a national computerized legal database maintained by the West Publishing Company, **WESTLAW**, with opinions from both state and federal courts from 1971 through 1990.[7] The survey revealed 45 cases litigated in 38 states during those 20 years.

When patients' ages could be determined, 58 percent were less than 39 years old, the mean age was 40 years, and all were less than 59 years old.

The patient presented with a painless mass in 65 percent of cases. Pain, skin changes, and breast discharges exemplified additional symptoms that were reported, however, in more than 20 percent of cases. The diagnostic evaluation was limited to a physical examination in 51 percent of patients. Among the 20 mammograms that were obtained, 16 (80 percent) had been considered normal.

The average delay in diagnosis was 15 months. In 32 cases where the stage of disease at diagnosis was available, there were two cases at stage I, 22 at stage II, and the remainder at stage III or IV. In 12 cases, metastatic disease or death occurred by the time of litigation. The cases involving death included two patients who had initially presented when pregnant.

Kern concluded with an examination of case factors for claims resolved by an indemnification payment in excess of $500,000. In his opinion, those cases tended to involve the youngest patients, pregnant patients, and patients experiencing the longest delays.

Henderson and Danner published a review derived from their clinical and legal experiences highlighting certain "pitfalls" in the diagnosis and management of breast cancer.[8] They acknowledged that the treatment of this disease, whether by surgery, radiation, chemotherapy, or other measures, had been the source of some malpractice litigation. They were careful to stress, however, that the current frequency and severity of breast cancer malpractice claims overwhelmingly rest with those concerning delayed diagnosis, "... the most common source of malpractice complaint among patients with breast cancer."

They also emphasized that a physician's desire to reassure a patient may prove troublesome. "This very admirable and laudatory trait leads to problems when such reassurance subsequently proves inappropriate. It is recommended that the physician explain how difficult breast cancer is to diagnose and assure the patient that no one will in any way be critical if the patient calls repeatedly because she is concerned .... For some, breast self-examination alone can be a source of anxiety."

Although screening patients may lead to malpractice claims, the authors noted how much more frequently the critical clinical encounter was the evaluation of a patient who reported the presence of a breast mass, especially when a biopsy was not performed. They specified what they considered adequate medical documentation upon clinical presentation for the patient's history and the physician's physical examination. Mammography may be obtained to evaluate the remaining ipsilateral breast tissue and the opposite breast, however, "with rare exceptions, the results of a mammogram should not dissuade a physician from proceeding with planned biopsy."

Similar to classic textbook exhortations,[9] the authors stipulated that "the diagnosis of breast cancer is only positively made by a microscopic analysis by a pathologist." They also advised practitioners on the appropriate responses to positive and negative biopsies, the variant results of cyst aspiration, the frequent need for needle localization for biopsy of isolated suspicious findings on mammography and measures to take to avoid the difficulties that these tiny lesions can cause with missed biopsies. Finally, they emphasized the need for clarity, comfort, counselling, and careful guidance during follow-up and re-evaluations.

THE 1995 PIAA STUDY

The Physician Insurers Association of American (PIAA), as previously noted in this publication, was organized in 1977 as a national representative body of those medical liability insurance companies owned or

directed by doctors. There are now 47 medical liability insurance companies from across the United States that are constituent members of PIAA. Collectively, they insure more than half of the nation's private practicing physicians.

Since 1985, PIAA has maintained a central Data Sharing Project, a program created by 21 of the association's insurers, that collects a spectrum of data on all medical malpractice claims submitted to and closed by those companies to serve as a reliable and credible database for malpractice claims analysis and risk management. Presently, more than 117,000 claims and suits have been entered in that database. They include 35,700 paid cases with a total indemnity in excess of four billion dollars.

Since 1990, PIAA has annually published a series of focused reviews dedicated to particular categories of malpractice claims from the Data Sharing Project.

In 1995, the annual PIAA report addressed paid malpractice claims involving allegations of a delay in the diagnosis of breast cancer.[11] PIAA had previously published an analysis of the same type of claim in 1990. Breast cancer continued in 1995 to be the diagnostic condition for which a patient most frequently filed a malpractice claim against a PIAA member physician. Indemnification occurred in 44 percent of those claims, and the condition was second only to claims involving neurologically impaired newborns as the most expensive in terms of total indemnity paid. In the six-month interval prior to the 1995 report, the average indemnification for PIAA claims involving this condition exceeded $307,000.

There are 36 PIAA member companies that responded to a request to participate in the 1995 breast cancer study. They reported a total of 487 paid cases with incident dates after January 1985 that involved a delay in the diagnosis of breast cancer.

A key finding was that patients at presentation were relatively young, when the illness might not be suspected, when physicians might be less impressed by symptoms or findings, and when the disease can be more difficult to detect. More than 60 percent of patients were less than 50 years old, and their claims accounted for more than 71 percent of the total indemnity (Table 1).

Most commonly, in 60 percent of cases, the patient detected the lesion herself. A mass without pain was reported in almost 50 percent of cases, but patients with symptoms of pain and tenderness, with or without a mass, were reported in more than 25 percent of cases.

PIAA STUDY: CLAIMANT'S AGE
n=487

Age	Number of Claims	Percentage	Percentage of Indemnity
20-29	31	6.4	7.9
30-39	119	24.4	29.0
40-49	150	30.8	34.2
50-59	111	22.8	19.8
60-69	56	11.5	7.5
70-79	14	2.9	1.2
80-89	2	0.4	0.1
unknown	4	0.8	0.3

TABLE 1

Mammography was either negative or equivocal, when a lesion was present, in almost 80 percent of cases. These false negative or equivocal results appeared more frequently in women less than 40 years of age.

A total of 917 physicians and entities had been initially named in the 487 study cases, and payments were made on behalf of 675 defendants. The specialities with the highest frequency of paid claims reported were radiology, obstetrics gynecology, and family practice (See Table 2 on next page).

There were awards negotiated by settlement in 462 cases, with an average indemnity of $282,244. There were nine resolutions by arbitration-mediation, and only 16 cases (3.3 percent) were tried to a jury verdict, where the average indemnity was $869,766 and the associated defense costs were approximately $101,0000 for each trial.

In contrast with the 1990 study, the 1995 survey reported an average length of delay in diagnosis that had increased from 12.7 months to 14 months, an increase of average indemnity of 36 percent from $221,524 to $301,460, and that radiologists were among the named defendants in 21 percent of cases as compared to 11.4 percent. The latter might reflect, over time, the burgeoning utilization of mammography for both diagnostic and screening purposes.

PIAA STUDY: DEFENDANTS
n=675

Defendant	Number of Claims	Percentage of Indemnity
Radiology	165	20.5
Obstetrics/Gynecology	154	29.0
Family Practice	113	13.5
Surgical Specialties	97	17.0
Internal Medicine	61	7.3
Pathology	11	2.6
Other Physician	31	3.5
Corporation	30	5.6
Hospital	13	1.0

TABLE 2

DISCUSSION

Given the relative youth of the patients involved in breast cancer malpractice cases, a striking dissonance should be apparent between the demographics of these claims and the epidemiology of the disease.

With breast cancer having been diagnosed in approximately two million women in the United States over the last decade, one question concerns the proper focus for the attention justifiably devoted to this somewhat special population of several hundred malpractice claimants.

Further, our society's courts are apparently convinced that medical science now knows the complete natural history of breast cancer and that medical treatments of proven efficacy exist for this malignancy when timely diagnosed. Those convictions, however, suspect, are applied by the courts to support imposing liability through an arguably contrived syllogism that time is always of the essence in diagnosing this disease and, therefore, a "lost chance" for survival is real, material, and precisely calculable.[7,12,13]

The courts, however, have not misled themselves. Their convictions find initial voice in the occasionally untempered declarations of national cancer-related charitable organizations, the proclamations of federal cancer research agencies, the edicts of national medical specialty associations, and the opinions of readily available expert witnesses.

Recent years have witnessed no change in the mortality rate for breast cancer, while the reported incidence of the disease has climbed steeply. These statistics could be interpreted as evincing the curative effectiveness of available treatments upon timely diagnosis. Conversely, the data may reflect, once again, the irresistible influence of lead-time bias.

Breast cancer that appears in patients who later file malpractice claims may be biologically different, or those patients could react to the threat of the disease with special host factors. In either context, the rote application of biostatistics derived almost completely from other breast cancer patients may not be justifiable.

Regardless, practitioners, as noted at the conclusion of the PIAA study, would be wise to take heed of certain tenets derived from these liability cases:

- Breast cancer can occur in relatively young patients, those in their 20's and 30's, more when pregnant.
- The clinical presentation of breast cancer includes patients with painful or tender breast lesions.
- Diagnostic mammography does not currently exist, and clinicians should consider those terms mutually exclusive.
- Breast cancer can be diagnosed now only upon the satisfaction of histopathologic criteria.
- The potential for false negative biopsies is heightened when evaluation small breast lesions, and special procedures, such as tissue specimen radiographs and early repeat mammograms, may be indicated.
- Careful counseling and assiduous reevaluation may be necessary to clarify the diagnosis of breast cancer, a disease where patient denial should be anticipated.

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